REMARKS

Claims 1-4 and 7-9 are pending.

The is responsive to the Office Action dated September 3, 2002. Applicants, through their attorney Yunling Ren, had an telephone interview with the Examiners Emily Le and Hankyel Park on December 2, 2003 with respect to the 9/3/02 Office Action. The telephone interview is substantively described as follows:

The Examiner rejects claims 1-4 and 7-9 as containing "new matter" on the ground that there are no supports in the specification for "concentrations between 0 to 100% by volume", for "parts by weight" and for "a smaller amount of said RT-PCR product correlates a lower level of said gene expression".

As to "parts by weight", the Examiner indicates in the Office Action that the replacement of "parts by weight" by "grams" will overcome the rejection to this term. Accordingly, applicants have amended the claims 1 and 7 by changing "parts by weight" to "grams". Applicants believe that such amendment does not change the scope of claims 1 and 7 since "parts by weight" and "grams" are considered to be synonymous in this context.

As to claim language "concentrations between 0 to 100% by volume" and "a smaller amount of said RT-PCR product correlates a lower level of said gene expression", applicants have amended this claim language by deleting the term "by volume". Applicants also directed the Examiners' attention to Figs. 1 and 2, which clearly shows that the CCR5 gene expression decreases (the panels on the right) compared to the control panels (on the left) when the concentration of Reticulose (Product R) increases from 0% to 100%. In the telephone interview, the Examiners agreed that these figures provide the requisite support for the above claim language at issue. Thus, the new matter rejection should be withdrawn.

The Examiner also rejects claims 1-4 and 7-9 as being unenabling since the Examiner believes that the specification does not provide support for the claim language "physiologically acceptable pH" in step f', "concentrations between 0 to 100%" in step c of claim 1 and in step b of claim 7, "predetermined progressively increasing amounts of Product R" in step c of claim 1 and in step b of claim 7, "cooling the product" in step c', and "adding water" in step e'. These terms were discussed in the telephone interview and the Examiners suggested that amendments or explanations of these terms will overcome the rejection. Accordingly, applicants provide the following amendments and/or explanations:

As to "physiologically acceptable pH" in step f', applicants have changed the term to a specific pH range as suggested by the Examiner in the 9/3/02 Office Action, i.e. "pH 7.3 - 7.6".

As to "predetermined progressively increasing amounts of Product R" in step c of claim 1 and in step b of claim 7, applicants have deleted the phrase " predetermined progressively increasing", as suggested by the Examiner in the telephone interview, so that step c of claim 1 and step b of claim 7 are now clear, because only the amounts of Product R between 0 to 100%, not the frequency and rate of adding Product R, are required.

As to "concentrations between 0 to 100%" in step c of claim 1 and in step b of claim 7, the Examiner has acknowledged in the 9/3/02 Office Action that the specification provides Product R concentrations of 0%, 25%, 50%, 75% and 100%. Applicants explained to the Examiners in the telephone interview that these concentration standards are conveniently selected for the purpose of determining the correlation between the amount of Product R and its effect on the gene expression. Known to a person of ordinary skill in the art, it would make no difference if applicants have selected different concentration standards between 0 to 100% (e.g. 0%, 10%, 21%, 53%, 87%, etc. and 100%). The point is to create an artificial concentration

gradient to see the gene expression pattern. Selecting concentration standards in such fashion is a routine practice of those ordinary skilled in the art and it is commonly understood that the concentrations chosen in such way reflect the entire range of the concentration between 0 to 100%. The Examiners advised applicants in the telephone interview that such explanation would be sufficient to overcome the rejection.

As to "cooling the product" in step c', applicants have amended step c' to read "c') cooling the product from said step b' **for at least six hours at 3-8 °C**, said cooled product comprising solids;", by adding an additional limitation "**for at least six hours at 3-8 °C**", applicants have made it clear how the product should be cooled after autoclave. Known to a person of ordinary skill in the art, there are usually two ways of cooling an autoclaved material that is at a very high temperature as in the present application: 1) placing the autoclaved material at room temperature; and 2) placing the autoclaved material in a cold room, where the temperature is usually between 3-8 °C. Known to a person of ordinary skill in the art, the cooling rate is a function of the initial temperature (which is the temperature after autoclave) and the cooling temperature (3-8 °C), both are specified in the specification on page 9. The period of cooling is "at least six hours", which is sufficient to cool the product down to 3-8 °C from the temperature after autoclave. The method of cooling is not critical so long as the cooling temperature is between 3-8 °C for a sufficient period of time, i.e. at least six hours, a condition that is commonly used by a person of ordinary skilled in the art. The Examiners advised applicants in the telephone interview that such explanation would be sufficient to overcome the rejection.

As to "adding water" in step e', applicants have amended step e' to read "e') adding water to the product from said step d' **to create a final volume of about 5 liters"**. This language makes

the purpose of step e') more clear. Support for this addition can be found on page 9, line 19 of the specification.

In view of the above amendment and the remarks, applicants believe that the rejection under 35 U.S.C. 112, first paragraph, has been overcome. It is respectfully requested that the rejection be withdrawn.

For the forgoing reasons, claims 1 and 7 are in an allowable condition. For the same reasons, claims 2-4, which depend on claim 1, and claim 8-9, which depend on claim 7, are also in an allowable condition.

Respectfully submitted,
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